

Running Head: VR USE IN VACCINATION

Use of Virtual Reality to Decrease Pain and Anxiety During Vaccination

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Abstract

Vaccinations are routine procedures in pediatric offices, however studies have shown that most primary care settings offer little in the way of pain and anxiety management for the procedure. This lack of intervention combined with significant portions of the population suffering from needle fear and anxiety leads to vaccine hesitancy, delay, and refusal. One way to help this issue is the use of VR. This technology has been used to decrease pain and anxiety in adolescent patients during dressing changes, venipuncture, and vaccination for over 18 years. The costs of the technology have also decreased to make VR an affordable tool for primary care offices for use during vaccinations to help patients who have needle fear and anxiety. This project studied the affect VR has on the perceived pain of vaccination and the situational anxiety patients experience in a primary care office. A total of 104 subjects took part in the study, 52 using the VR during vaccination and 52 only experiencing standard office procedure. Analysis found that anxiety significantly decreased from 3.98 to 2.04 on numeric scales from 0-10 in subjects using the VR, $U=1057$, $p=0.000077$. Perceived pain levels also decreased from 3.06 to 2.31 on numeric scales from 0-10, $U=750.5$, $p=0.052$. Regression analysis taking into account higher baseline anxiety, number of shots, and higher frequency of more painful shots in the VR group showed that the use of the VR did lead to a significant reduction in pain, $\beta=-1.12$, $t(103)=-3.85$, $p=0.0002$. These data show that the VR is an effective tool for vaccine pain and anxiety management, and primary care offices should be encouraged to implement the VR in their practices.

Keywords: Virtual reality, VR, pain management, anxiety, vaccination, needle fear

Background and Significance

History and Efficacy of Vaccines

Before the advent of modern medicine, thousands of people died from infectious diseases like smallpox. Physicians studied to look for ways to prevent these illnesses, and Edward Jenner was one of those physicians. In the 1790s, he noticed that cow maids would not get smallpox during outbreaks, and if they did their cases were mild compared to others. He theorized that being infected with cowpox (vaccinia virus), a similar yet less virulent disease, conferred immunity to smallpox. To test his theory, he inoculated a boy with cowpox and showed that he was then immune to smallpox. In 1798, the first smallpox vaccine, a new word derived from the vaccinia virus, was produced and given to the public (Immunization Advisory Center, 2017).

Jenner was correct that exposing the body to similar, yet less or non-virulent particles, will confer immunity to the more potent strain. Vaccinations contain either sections or inactivated but still live forms of a given pathogen. The immune system will then recognize these foreign materials, mount an immune response, and develop memory cells so that the body will not be attacked by this pathogen again. Thus, when the body encounters the wild type virus or bacteria, it has already been exposed and stems off infection before the person becomes ill (Berkowitz, 2014).

Vaccines are extremely effective tools in preventing disease in the population. According to CDC estimates, there were over 1.1 million cases per year of diseases like measles, tetanus, diphtheria, pertussis, and polio in the mid-20th century. The acceptance of the modern vaccination schedule has drastically reduced the incidence of these diseases (CDC, 2017). Few primary care providers report diagnosing cases involving these highly

communicable diseases (Sy & Long-Martin, 2012). Given this evidence, vaccines are clearly a major tool for public health and one of the best medical advances of modern medicine.

Vaccine Fear and Hesitancy

Despite the success of vaccinations, many individuals fear inoculation. Beyond the unfounded fears that vaccines cause autism or other chronic issues (Maglione, et al, 2014), most children have a fear of the needles themselves. One study of over 1,000 children and their parents found that 63% of children and 24% of their parents have a fear of needles (Taddio et al., 2012). This fear can have biological effects on the children, with a study showing that children with a fear of needles reported 33% higher pain scores and had 38% higher levels of the stress hormone cortisol circulating in their blood after the procedure compared to children who do not have the same fear (Heden, von Essen, & Ljungman, 2016).

The fear of needles can lead to increased perception of danger of vaccines, hesitancy in getting vaccines, and vaccine non-compliance. The survey by Taddio, et al (2012) found that 7-8% of children are vaccine non-compliant primarily because of needle fear, and another 27% said that they delayed vaccines because of needle fear. This finding was reaffirmed with another study that found a positive correlation between needle anxiety and vaccine delay or refusal for both children and adults (McMurtry et al., 2015).

Patient vaccine anxiety can also have a negative effect on healthcare workers. In a study by Ives and Melrose (2010), 35 public health nurses were surveyed regarding the effects of patient vaccine anxiety and the role the nurse plays in routine inoculation. Nurses expressed concerns regarding the physical force needed to vaccinate a fearful child, lack of resources to reduce pain and anxiety as well as options to facilitate a more positive experience (Ives & Melrose, 2010).

Development of Virtual Reality

Since the dawn of photography, there have been attempts at using technology to create virtual environments. The first rudimentary virtual reality (VR) was the stereoscope, which was developed in the late 1800s and used specialized google to project complementary views to each eye to create a three-dimensional image of a new environment. This technology was perfected by View Master in the 1930s and is still a popular product for the company today (Franklin Institute, 2018). As technology and computers developed, so did VR. In the 1950s, the Department of Defense developed immersive flight simulators for training, with screens coordinated with motion to give the pilots a safe place to experience adverse events (BAA Training, 2015). Then, inventor Morton Helig took inspiration from the flight simulators and created “Sensorama,” where he timed movies to motion simulators so that people could feel like they were “in the movies.” Helig then combined the simulators with the headgear of the View Masters to create the first head mounted displays (HMD) commonly used with VR today (Franklin Institute, 2018). While HMDs were invented in the 1950s and developed further through the decades, the technology was always too expensive for the average consumer. Basic HMD models cost over \$10,000 in the 1990s, and even over \$2,000 in the early 2000s, and they needed to be connected to computers with high computing capacity (Bailenson, 2018).

The persistence of these high costs changed with the advent of the smartphone. The introduction of the iPhone, Samsung Galaxy, and other such phones gave users powerful processors in a portable, easily carried device. Google and Samsung both saw the potential of these devices and started developing HMDs that used the phone to do most of the work for creating a virtual environment (Bailenson, 2018). Google developed Cardboard, so named because the viewer is made of a simple cardboard box containing two focal lenses. Once the

cardboard box and lenses are assembled, any type of smartphone can be loaded with designated software and inserted into the box. The kit costs \$5-20 depending on the quantity purchased, giving consumers a low-cost entry into VR, but capacity of the programs is limited by the simplicity (Google, 2018). Samsung developed the Gear VR. The system uses Samsung Galaxy phones connected to a plastic shell with dual displays. The set uses the internal gyroscope of the phone to dictate how and when images are displayed to create the new, immersive environment. This system has a current retail price of \$99 (Samsung, 2018). These two options have created unprecedented access to this technology for the general public.

Use of VR in Reducing Procedural Pain

The decrease in cost for VR has spurred expanded use of the technology in many areas, including healthcare. This distraction technique is a well-known option for pain management, and the more engaged with the distraction the patient is, the better the pain reducing effects (Birnie et al., 2014). The immersive nature of VR makes it a particularly useful distraction tool, even when compared to other video game systems (Bailenson, 2018).

Medical trials have shown how successful VR can be in pain control. One of the first trials for VR use in pain control was in a 16-year-old burn patient. He had previously used a console game system during dressing changes but reported that he was conscious of the procedural pain 95% of the time when using it. When he used VR, he reported he was conscious of the pain only 2% of the time, and he experienced a 47% drop in reported pain (Hoffman, Doctor, Patterson, Carrougher, & Furness, 2000). Further studies in burn patients showed that VR not only decreases reported pain, but also decreases use in pain medication. Entonox is a mixture of nitrous oxide and oxygen commonly given to burn patients for pain relief. Patients using VR were significantly less likely to use Entonox during a dressing change

compared to children using other methods of distraction (Kipping, Rodger, Miller, & Kimble, 2012).

Since those early studies, the use of VR in pain management in pediatric patients has expanded. It has successfully reduced pain during chemotherapy, dental procedures, central line access, and venipunctures (Won et al., 2017). However, these studies were almost exclusively done in the in-patient setting, and all using the Samsung Gear VR or a custom computer-based system. One study done in an outpatient clinic looked to see if VR reduces pain during influenza vaccination (Silverberg, Silverberg, & LaPuma, 2017). The researchers used Google cardboard during vaccination for 244 children. They found that patient reported post-vaccine pain was reduced 45-74%, time taken for the procedure was reduced per nurse report, and all parties (patient, nurse, and parent) reported a less stressful experience while using the VR (Silverberg, Silverberg, & LaPuma, 2017). Clearly, VR can be a beneficial tool in decreasing procedural pain for pediatric patients.

Problem Statement

The lack of interventions offered in primary care offices to reduce vaccination pain and anxiety can lead to public health consequences when patients delay or forego vaccines due to their fear. VR has been shown to be an effective tool in decreasing pain and reducing the stress involved in medical procedures. However, VR has not been used for vaccinations, except for one study. Thus, the clinical question is, does the use of virtual reality decrease pain and anxiety in pediatric patients receiving vaccinations in the outpatient setting compared to standard practice?

Needs Assessment

The public health implications of vaccine delay and refusal are significant. Individually, patients who refuse or delay vaccines are put at greater risk for contracting preventable infectious disease. These diseases can lead to serious illness and lifelong health consequences if contracted (Williamson & Glaab, 2018). Globally, decreases in vaccination rates lead to a reduction in herd immunity, a concept where enough people are vaccinated that diseases do not spread amongst those not vaccinated in the population (CDC, 2018). The loss of herd immunity allows diseases once thought to be eradicated to return. These pathogens can infect not only unvaccinated individuals, but also those too young to receive the vaccine, the immunocompromised who have lost their immunity, and those for whom the vaccine does not trigger an adequate immune response (Williamson & Glaab, 2018).

In the United States as a whole, vaccination rates vary depending on area and type of vaccine. The CDC reported that 72.2% of children have completed the main 7-vaccine schedule from 2016-2017 data (CDC, 2018). The site for this project was in Millburn, NJ, in Union County. In New Jersey, according to the latest reports from 2014, 95% of children in the public-school system were fully vaccinated (NJ Department of Health, 2014). Union county specifically had 95% vaccination for Kindergarteners, but only 93.8% rates of full vaccination for all public-school students in 2014 (NJ Department of Health, 2014). From this data, the population in the project areas were well vaccinated compared to the whole country, but lower than the state average. Also, the drop from 95% in Kindergarten to 93.8% for all students shows that the older children this project targeted may be failing behind on their required vaccinations. This project aimed to not only improve the subjects' experience during vaccination but maintain and possibly improve the high rates of vaccination in this area.

The public health risk of vaccine hesitancy and refusal are dire, and healthcare workers need to implement any change they can to ensure individuals receive their vaccinations. Unfortunately, addressing needle pain and anxiety is not usually done in primary care offices. A systematic review of vaccine pain and anxiety studied showed, over the course of several studies, parents feel that their child's pain is not addressed during vaccinations and they think their only recourse is to delay or separate vaccines. The review also found that while pharmacologic interventions, such as instructions to give Tylenol or Motrin, were common, other methods to reduce stress were rarely utilized (Taddio et al., 2009). Another study that directly surveyed 38 primary care physicians reflected those same findings, with only 4 of respondents using any form of pain control in office, and only one respondent used any intervention besides Tylenol or Motrin (Brady, Avner, & Khine, 2011).

Objectives and Aims

There were two main aims of this project:

- 1) Short term: To decrease pain and anxiety for a specific vaccination encounter
- 2) Long term: To encourage vaccine compliance and increase vaccination rates

To meet these aims, the project will meet the following objectives:

- 1) Assess the situational anxiety levels and post-vaccination pain of subjects using the VR will be compared to control groups with standard care using appropriate statistical analysis.
- 2) Analyze future vaccination habits in post-VR survey using appropriate qualitative analysis
- 3) Report project results to encourage further implementation of the VR in primary care offices to increase vaccination compliance

Review of Literature

To best understand the use of virtual reality in combating pain and anxiety during vaccination, a thorough search of available literature was conducted. The results in these published papers contain the latest knowledge and evidence-based practices which can be utilized in updating current clinical practice.

Search Methodology

The literature review search was carried out using the PubMed database. The first search consisted of finding articles on the topic of virtual reality as a pain control method in children. The MESH terms “pediatrics,” “pediatric,” “child,” “children,” “pain control,” “anxiety,” and “virtual reality” were entered in to an advanced search [((virtual reality) AND ((pediatrics) or (pediatric) or (child) or (children))) AND ((pain control) or (pain management) or (anxiety))]. The search resulted in 27 papers, which was further reduced to 20 papers by limiting the search to only the past ten years. Of those 20 papers, ten involved treating pain in pediatric burn victims, five were review articles, two focused on procedural pain, one focused on venipuncture, one on dental procedures, and one focused on the treatment of chronic pain. Additional academic papers were found by reviewing the references in the articles on the use of virtual reality in procedures and venipuncture, and the review articles because those papers were most related to the research topic of VR and vaccination.

Pain During Vaccination

Pediatric patients receive 28 injectable vaccinations from birth to 18 years, not including annual influenza vaccines (CDC, 2018). A recent review article by pain management experts explored the evaluation of pain in pediatric patients during vaccinations. They found that in general, vaccination pain is usually treated in the home using analgesics like Tylenol or Motrin,

but very little is commonly done during the procedure itself to reduce pain and anxiety. The authors also found that high anxiety associated with vaccinations leads to increased vaccine refusal rates both for the patient themselves and for children of people with high vaccine anxiety (McMurtry et al., 2015).

Another study performed a survey of primary care pediatric physicians to determine their view points about vaccination pain. Seventy physicians participated in the survey, and on average they believe that patients experience pain of 5.7 on scale of 1-10 and anxiety of 7.7 on scale of 1-10. However, only eight of those physicians, or 11%, included pain management during venipuncture in their plans of care, and that usually involved giving Tylenol or Motrin in the office rather than having a formal plan using distraction or other methods (Brady, Avner, & Khine, 2011).

Virtual Reality in Pain Management

A systematic review and meta-analysis evaluating distraction tools in alleviating pediatric pain found that the more immersive the experience, the greater the effect the distraction has on reducing pain and anxiety. Because VR is an immersive experience, the authors found that it was better at reducing perceived pain and anxiety compared to other distraction tools like television or standard video games (Birnie et al., 2014).

The use of VR as a distraction tool for pediatric patients was pioneered with burn dressing changes. VR allows the patient to be distracted and focused elsewhere during the procedure, thus decreasing the pain of the procedure (Won et al., 2017). One randomized control trial involved 41 pediatric burn patients. They found all pain measurements (self-report, nurse FLACC and vital signs) were lower in groups using the VR during dressing changes than control, however none of the self-report results reached statistical significance (p values range

from 0.16-0.75). The one result that reached statistical significance was the nurse FLACC assessment, which was 3 for standard treatment group and 1.9 for the VR group ($p=0.02$). Also, another measurement that reached statistical significance was the use of the pain medication Entonox, otherwise known as laughing gas and a common analgesic in burn victims, was significantly lower in VR group than in the control ($p=0.05$) (Kipping, Rodger, Miller, & Kimble, 2012).

Another trial tested the technology with 65 patients with lower limb wounds that needed chronic dressing changes, similar to burn dressings. The participants were educated on the VR for about 10 minutes before the procedure, then allowed to use it up to 5 minutes after the completion of the dressing change. In this study, they found that pain during dressing change decreased by an average of 42% in the VR group compared to standard distraction, as measured before, during, and after dressing change, all statistically significant with p values ranging from <0.001 to 0.034 (Hua, Qiu, Yao, Zhang, & Chen, 2015).

Other researchers started examining the role VR could play in venipuncture, such as IV insertion. One of the first RCT for examining IV insertion was done with 20 pediatric patients. They found that the control group had 4-fold increase in pain during IV placement compared to VR group: control group went from an average of 0.6 before the venipuncture to 2.4 immediately after, a difference of 1.8, while the VR group went from 0.8 before to 1.8 after, a difference of 1.0 on a scale from 1-5. Comparison of the difference approached significance with $p=0.6$. The results of this study were not statistically significant probably due to the low number of participants. Based on nurse assessment, VR group also showed evidence of lower anxiety and more satisfaction with the procedure (Gold, Kim, Kant, Joseph, & Rizzo, 2006).

Another study looked at the use of VR in intravenous (IV) access or port-a-cath needle

insertion in oncology patients. Pain level was assessed using a color analog scale before, during and after the port needle insertion. They did not find any statistically significant differences between the case and control groups in quantitative pain values, however they note that the pain scores for both groups were low, on a range from 2-3 out of 10, so the effects of any intervention would be difficult. The researchers did not specifically assess for procedure anxiety. They also did a qualitative analysis of questionnaires after the project showed generalized support of the VR and that patients reported better general experiences with it versus standard distraction (Nilsson, Finnstrom, Kokinsky, & Enskar, 2009).

A more recent RCT done with IV insertion involved 143 sets of patients, parents, and phlebotomists during laboratory blood draws in a regional hospital. VR significantly reduced pain and anxiety in the patients from self-report data of patient ($p=0.006$). Secondary analysis examined the effects of VR while looking at base anxiety levels regarding the blood draw procedure. The children with high anxiety had significant, large decreases in pain during the insertion ($p<0.001$). For children with low pre-procedural anxiety, the effects of VR were not significant ($p=0.97$). Thus, they concluded that VR works best for children with higher baseline procedural anxiety (Gold & Mahrer, 2017).

Finally, there has been one documented study looking specifically at the use of VR during vaccination. VR was used at an outpatient influenza vaccine clinic on 244 children, aged 5-16. Researchers found that using VR for approximately 30 seconds before, during, and 30 seconds after vaccination was associated with a 45% to 74% decrease in pain using Wong-Baker scale ($p<0.03$). They also surveyed the nursing staff who gave the inoculations and the patients' parents. Both groups said that the procedure was easier and less anxiety-inducing than simply giving the vaccination (Silverberg, Silverberg, & LaPuma, 2017).

Literature Summary

The review of literature supports the need for pain and anxiety intervention during vaccination. Currently, very few if any primary care offices offer pain and anxiety reduction measures during vaccination, despite evidence showing that patients will hesitate, delay, or refuse vaccines because of their fear. VR is a state of the art tool that has become affordable enough to utilize in primary care. Patients, families, and nurses all expressed favorable views on using VR to reduce pain and effectively distract patients away from medical procedures. In the Silverberg, et al (2017) study that used VR in vaccination, they found significantly reduced pain scores and increased satisfaction with the procedure. Thus, the literature supports the idea of further implementing this intervention at other primary care sites.

Theoretical Framework

Implementing a change in practice can be very difficult in healthcare. Starting the use of VR challenges the status quo for primary care offices, so using a theoretical framework can provide guidelines and processes to make the effort more streamlined and effective. A framework that is well suited for this task is the Knowledge to Action (KTA) process.

Theory Details

The KTA method emphasizes the implementation of knowledge while considering multiple stakeholders (Graham et al, 2006). It has two phases, knowledge creation and knowledge application. The creation phase covers the background knowledge of an issue. It is divided into three phases: generation, synthesis, and tools/products. Following this framework, first the basic research is done and distributed through journals and meetings (generation), then review papers in a given subject highlight the most important and repeated findings (synthesis), and finally tools or products like formal guidelines, are created for the end user (tools) (Graham

et al., 2006). For this VR pilot project, the creation steps have been completed through published research. While no specific tools have been generated, researchers have published their methods and protocols for use of VR.

The next phase of KTA is application, and it is the key phase for the VR pilot project. This stage focuses on the implementation of new practice based on the knowledge from the creation phase. This phase has seven stages: problem identification, adaption of knowledge, barrier assessment, implementation, monitoring, evaluation, and sustaining knowledge. First, the issue must be recognized in practice outside of the research realm. Without realization that the problem exists, change in practice will not be adopted in the long term (Graham et al., 2006). Next, the tools/products need to be adapted to fit local needs and barriers, such as stakeholder buy in, need to be identified. The next phase is implementation, with the project goals “going live” in the local setting. After implementation, the project team needs to evaluate the implementation to ensure that the change is progressing as planned or if additional barriers have been found. Finally, the whole process should be reviewed to determine if the project was successful or new knowledge needs to be generated to resolve the issues (Graham et al., 2006).

This type of framework is ideal because this project needed to consider input and opinions of multiple parties, from the medical assistants who will be implementing the system, to parents caring for their child, to the patients themselves. Educating all the stakeholders about the research behind the project, and directly addressing their concerns, increased of success of the pilot project and future adoption of VR into practice beyond the pilot.

Use of KTA in Project Implementation

In terms of VR use in pediatric pain management, there has been a substantial amount of

knowledge generated in the creation phase. While no specific tools exist, that evidence of its benefits is sufficient to implement in a local practice to add to the general knowledge base at the conclusion of the pilot project. A visual representation of this process is in appendix A.

As for the application phase, the project progressed along the following steps. First, the issue of pain and anxiety was identified as an issue at the targeted implementation facility through a needs assessment. Next, the VR system was adapted for this facility and the project goals were introduced and explained to staff members, namely physicians and medical assistants. This education was done during staff meetings or lunch and learn to include as many stakeholders as possible. During the meeting, the staff were surveyed to identify issues are barriers they perceive that would hinder successful implementation of this project. Staff concerns were then compiled, and mitigation plans were developed based on their concerns (Table 1) The improvements were presented at the next staff meeting for further comment to ensure staff buy-in for the project.

After the staff were educated and the VR system procured, the project entered the implementation phase of KTA. Patients were chosen based on convenience sampling. These patients and their families were introduced to the project for their consent and assent. Before the vaccination, the subjects' anxiety was assessed using a numeric scale rating scale, where 0 is calm and 10 is panic. This type of numeric scale has been studied and validated for assessing situational anxiety for children over the age of 7 (Crandall, Lammers, Senders, Savedra, & Braun, 2007; Ersig, Kleiber, McCarthy, & Hanrahan, 2013).

After using the VR system during vaccination, the subjects were reassessed for the anxiety they felt during the procedure using the same tool. They were also assessed for the pain they felt during the vaccination using a numeric 0-10 scale, with 0 being no pain and 10 being

the worst possible pain. The numeric scale for pain has been a well-used, frequently validated tool for assessing pain in children over the age of 6 (Manworren & Stinson, 2016; McGrath, 1989; Page et al., 2012; Tsze, von Baeyer, Pahalyants, & Dayan, 2018). See appendix B for tool visuals. The VR group data were compared to a control group, which followed the same assessment but only experienced standard office procedure during the vaccination. Monitoring by the DNP student occurred as data were collected to ensure that implementation was consistent over the course of the pilot.

Implementation of new evidence-based practice can be difficult. In many cases, the knowledge is disseminated through publication or presentation, but practice does not change. The KTA program takes knowledge translation further, incorporating the development of translation tools or programs as one of the integral steps of knowledge generation. The program links benchwork research with a detailed and effective project implementation framework through its action phase. The use of this framework helped guide the clinical implementation of VR use in pediatric patients in controlling their pain, anxiety, and minimizing their discomfort during vaccination.

Methodology

Setting

The project took place in a suburban pediatric primary care office in Milburn, Union County, NJ. The office has approximately 10,000 patients, and approximately 7,500 within the age range of this study.

Study Population

The project targeted children ages 10-21 who received at least one vaccination. This age

range was selected based on the age range of previous studies using this system (Arane, Behboudi, & Goldman, 2017; Gold, Kim, Kant, Joseph, & Rizzo, 2006; Gold & Mahrer, 2017; Kipping, Rodger, Miller, & Kimble, 2012; Nilsson, Finnstrom, Kokinsky, & Enskar, 2009).

Exclusion criteria were history of seizures, motion sickness, or developmental impairment that will inhibit them from using the device. These criteria are based on the user manual warnings and recommendations (Samsung, 2018). Non-English speaking patients were excluded secondary to the examiner's lack of knowledge or ability to translate any other languages spoken in the site and lack of language support on the VR system.

Study Interventions

The project took place during a scheduled office visit, either for physical or follow up, when patients received a vaccination. Because of convenience sampling and the limited project population, this vaccination may be any that the child is due to receive that day, however the type of vaccine subject received was noted. The DNP student reviewed records for those due for vaccination that met all inclusion and exclusion criteria. Potential subjects and their families were educated on the study and informed consent was obtained by the DNP student during the period between when the medical assistant (MA) took vital signs and when the provider was able to see the patient, a period of about 10-30 minutes. Once the subjects and parents signed consent and assent forms, subjects provided their ages, sex, and race/ethnicity, and the DNP students assessed them for their pre-vaccine level of anxiety (how they generally feel about vaccines) using the numeric scale (0-10) during this interlude (Appendix B).

Once the provider appointment was complete, the DNP student returned to the room with the MA. The subjects were introduced to the Samsung Gear VR and the game Ocean Rift, where the user is able to explore an underwater ecosystem filled with fish, dolphins, and sea turtles.

This system and game were chosen because it has been successfully used in previous VR pain studies (Gold & Mahrer, 2017; Silverberg, Silverberg & La Puma, 2017; Won et al., 2017). The test subjects used the VR for 60-90 seconds before the vaccine, and 30 seconds after, for a total of up to 2 minutes using the equipment. Once the equipment was removed, the subject was asked to state their level of anxiety during the procedure using the numeric again and quantify the pain of the vaccine also using the numeric (0-10) scale for pain (Appendix B). Finally, the subject and parent were asked “What are your thoughts on this experience?” to obtain qualitative assessment of the project.

Control subjects followed the same pre-provider activities, where they gave consent, demographic information, and baseline anxiety was assessed using the same numeric as the test group. Then, when the DNP student and MA returned with the vaccine, these subjects only experienced office standard treatment during the vaccine, which were mostly verbal instructions to not watch the procedure and verbal reassurance. After the vaccination, these subjects were asked to assess their pain and anxiety using the same tools as the test group.

Outcome Measures

The target outcomes for this project were assessing pain and anxiety levels during vaccinations immediately following the completion of the procedure. These were measured with numeric 0-10 scales, where 0 is calm/no pain and 10 is panic/worst possible pain (Appendix B).

Benefits/Risks

The risks of this project were minimal. According to the Health and Safety manual of the Samsung Gear VR, 1 in 4,000 users experience side effects such as motion sickness, dizziness, headache, and sense of claustrophobia. The manual also states that the technology has been shown to induce seizures, and the incidence is more common in children younger than 20 than in

adults (Samsung, 2018). Because of these risks, any potential subject with a history of motion sickness, claustrophobia, or seizures were excluded from the study.

There is also a risk of transmitted infection from multiple users of the same product. According to the manufacturer, the unit can be cleaned using an alcohol-based cleanser (Samsung, 2018). A study on the use of alcohol-based cleansing wipes on medical devices found they are effective in reducing 99% of bacterial colonies of common skin pathogens *Staphylococcus aureus* and *Acinetobacter baumannii* within 10 seconds of wiping (Sattar et al., 2015). Therefore, to reduce the risk of infection, the unit was cleaned with alcohol wipes after each user.

Finally, there was a risk that personal information could be inadvertently lost or accessed by an unauthorized user. To mitigate this risk, only the consent forms and ID code link spreadsheets contained subject names. The physical papers were kept in a locked file cabinet in the project chair's office at Rutgers University. The electronic ID code spreadsheet was encrypted and saved on a password protected laptop. The main data files for the project were saved in a different spreadsheet from the ID codes, and only contain depersonalized data. These files were also encrypted and saved on a password protected laptop.

Subject Recruitment

The project was advertised in the waiting room of each site, with all materials obtaining prior approval by the Rutgers Institutional Review Board (IRB). The advertisement included a basic description of the projects and dates when the data collection was happening in that office. The final approved version of advertisement is in appendix C. Office staff were also given basic information about the study, so they could answer questions if the DNP student was not in the office that day.

In addition, subjects were recruited through identification through convenience sampling. The DNP student identified any patient who will be receiving a vaccination during that office visit and met the inclusion criteria. The patient and parent were then given a description of the project and will be asked if they would like to participate.

Consent Procedures

For those willing to participate, full informed consents and assents for adolescents were obtained using Rutgers IRB-approved forms (Appendix E). Consent for the project took place after vital signs and weights are taken by office medical assistants, while patients and families waited for the medical provider for their physical, about 10-30 minutes depending on the schedule.

Subject Costs and Compensation

Subjects did not incur any costs by participating in this project, and they were not compensated.

Project Timeline

Rutgers IRB approval for the project was obtained in August 2018, and data collection started in September 2018. Data collection finished in November 2018, and analyses were completed in December 2018. Final presentation was in January 2019 (Appendix F).

Resources Needed/Economic Considerations

This project was self-funded. New VR equipment cost \$99 plus tax, and the Ocean Rift game cost \$6.99 plus tax. A personal phone was used to power the device at no additional cost to the project. Cleansing alcohol wipes cost approximately \$10. All printing was done at Rutgers University, with a cost of \$0.03 per page, total approximately \$40. Total budget for this project was approximately \$163.

Evaluation

The success of the project was determined based on the specific aims. For the short-term aim of reducing pain and anxiety, if the subjects using the VR demonstrate lower procedural anxiety and post-vaccine pain, the project can be deemed successful. The long-term aim of increasing vaccination compliance cannot be accurately evaluated without a future retrospective chart study on subject vaccine compliance. However, future use of the VR, and thus acceptance of future vaccinations, can be inferred through subjects' positive responses to the open-ended question about their experience and can be easily replicated.

Data Maintenance/Security

Data security was also a priority for this project to maintain subjects' confidentiality. First, only the consent, assent, and subject ID code spreadsheet contained personal identifier (name). These will be on physical papers which will be stored in a locked file cabinet at Rutgers University. The subject ID code spreadsheet will be destroyed once data entry is complete. Digital databases containing individual level, de-identified data will be encrypted, password protected and stored on a password protected laptop. Only members of the research team (DNP student, chairs, and academic advisors) were allowed access to the individual level data.

Data Analysis & Findings

A total number of 104 subjects participated in this project, with 52 control subjects experiencing only standard office procedure during their vaccination and 52 using the VR while receiving their vaccinations. The groups were generally similar in race, age and gender composition, however of note the VR group had a higher baseline anxiety level and received a higher average number of vaccines (Table 2).

Data were analyzed using the statistics program SPSS from IBM (version 25). Analysis concentrated on the difference in pain, procedure anxiety, and change in anxiety between baseline and procedure. Descriptive statistics showed that in this sample set, none of these three variables are normally distributed, so data were analyzed using the non-parametric independent sample test, the Mann-Whitney U. This analysis showed that the change in procedure anxiety (control=3.98, VR=2.04) and decrease in procedure anxiety from baseline (control=0.15, VR=2.62) were both statistically significant ($U=750.5$, $p=0.000077$ and $U=561$, $p=0.0000002$ respectively). The difference in pain between the control group (3.06) and VR group (2.31) was approaching significance ($U=1057$, $p=0.052$) (Table 3).

Further analysis focused on identifying factors that could influence pain and anxiety in this data set. Correlation studies using non-parametric test Spearman's rho were performed looking at the correlation between pain/anxiety and age, gender, race, baseline anxiety, and each specific vaccine (Table 4). In summary, race, age, gender, and most vaccines were not associated with higher pain or anxiety. Higher baseline anxiety was associated with increases in both procedure anxiety and pain. However, for pain, the number of vaccines, and the specific vaccines HPV and meningitis B were correlated with higher pain scores while those variables were not associated with increased anxiety. As noted before, the VR group had higher baseline anxiety, higher number of vaccines administered, and higher incidence of administration of HPV and meningitis B vaccines, all variables that were significantly associated with increased pain in this dataset. Stepwise linear regression analysis was performed to account for these factors that would increase pain. After controlling for these factors, the difference in pain between the control group and VR group became statistically significant ($\beta= -1.001$, $t(103)= -3.858$, $p=0.001$, Table 5). In these models, number of vaccines was correlated with both vaccine anxiety

(collinearity=97.6%) and receiving a painful vaccine (collinearity=96%), so it was excluded from the analysis.

In addition to pain and anxiety levels, feedback was requested from both subjects and parents on their experience with the VR. Qualitative data analysis of this feedback produced five major themes: enjoyment of the experience (82.7%), statements that the VR made the experience better (59.6%), surprise in the effectiveness of the VR (32.7%), requests for future use (9.6%), and remaining or increased anxiety because of the VR (7.7%) (Table 6).

Recommendations & Discussion

Analysis of Aims and Objectives

The main aim for this project is to reduce pain and anxiety for children receiving vaccinations. The data clearly show that this goal was met. Anxiety was reduced by half and pain by about 25%, both statistically significant. Qualitative data analysis shows that subjects and families were aware of the benefits of using the VR directly after their experience, with 93% of participants expressing enjoyment and satisfaction with the experience.

The secondary, long-term aim was to increase vaccine compliance and vaccination rates. These data clearly show the effectiveness of the VR in vaccine anxiety reduction. While this project did not directly assess for future actions, about 10% of the participants directly said they want to use the VR in the future, implying their willingness to receive vaccinations in the future. Further research can quantify increased vaccination compliance from this project through retrospective chart studies.

Facilitators and Barriers

All projects have facilitating factors that help achieve objectives and barriers that can prevent some level of success. Overall, this project was helped greatly by almost universal staff buy-in at the primary care practice, enthusiasm of the patients and parents in support of research, and the attractiveness of the intervention for pediatric patients. Staff were enthusiastic about implementing the VR, especially after they were educated on the goals and were able to try it for themselves. They actively helped the researcher in identifying potential research subjects and were active in making sure all research objectives were met with each subject. In addition to staff enthusiasm for the project, patients and families were very supportive of research as well. Even if sorted into the control group, and thus not experiencing anything outside of the general office experience, subjects and families spoke positively about their participation in research and supportive of the project's goals. Finally, the attractiveness of using the VR helped a great deal in recruiting pediatric patients to the project because they wanted to play with the new technology. If the intervention had not been so attractive to the pre-teen/teenage group, subject recruitment may have been much more difficult.

That being said, the project was not without barriers. The most significant barrier was VR start up time. If the VR was not used for 20-30 minutes, the game would shut down and would need to be restarted. While this process only takes 3-5 minutes, that is precious time in a busy practice, where time is of the essence. If staff did not notice that the system restarted, it led to a delay in administering the vaccine so that the subject could use the VR. In addition to the system restarts, extended use of the VR drained the battery of the smartphone powering the device, necessitating charging breaks. These two issues can be mitigated in practice by having the device charging until it needs to be used. Then, the game can be booted up while the staff draw up

vaccinations. By using this workflow, there would be no unnoticed system restarts and battery life can be maintained.

Unintended Consequences

While the project was successful in achieving objectives, there were two unintended consequences for the use of the VR. First was one patient experienced syncope when taking off the head set. Neither he nor his father disclosed that he was prone to syncopal episodes with vaccinations prior to VR use, and he received the HPV vaccine, which is known to induce syncope (CDC, 2015). With this situational background, it is uncertain if the VR was a trigger for the syncopal episode or if it would have happened regardless, but it was an unintended experience for the subject while participating in the project. Second, four of the 52 VR subjects (~7%) experienced increase anxiety and fear of vaccination while using the VR. They both stated that by not being able to see what was happening, they became more fearful than if they were able to see the procedure. For future implementation, children should be offered the vaccine, but should be allowed to take it off if the device induces greater fear during the procedure.

Implications

Clinical Practice

This project shows VR is an effective, inexpensive pain and anxiety management tool that is attractive to patients. By implementing the VR into practice, clinicians will be able to better manage their patient's pain and anxiety with vaccination. This is a tool that not only works, but patients want to use while getting vaccinated. If the data from this pilot holds true for the population at large, then rates of vaccine hesitancy and refusal will most likely decrease because the patients will have a more pleasant, less stressful experience getting their vaccines.

With greater vaccination rates, both personal and public health will benefit from greater disease prevention.

Healthcare Policy

There are currently no standards in place for pain and anxiety management during vaccination from medical organizations. However, the National Association of Pediatric Nurse Practitioners (NAPNAP) has an Immunization special interest group that currently developing a vaccine pain management tool kit. The group is planning to include VR in this tool kit (C.Cairns, personal communication, 2018). Through dissemination of this tool kit, pediatric nurse practitioners will become aware of this option and may implement it in their practice.

Quality & Safety

An important consideration for any tool being used in a primary care setting to ensure quality, safe patient care and prevention of disease. Through reducing pain and anxiety during vaccination, and in turn reducing needle fear, patients may be more likely to accept future vaccinations with fewer hesitations or refusals. Increasing vaccination will further public health goals of protecting the population from communicable disease. It will be necessary to train healthcare professionals in maintaining proper hygiene procedures when using the VR in the office. For example, they will need to use proper headset covers and ensure cleaning between patients so that the VR will not be a source of disease transmission.

Education

As previous literature has shown, while providers recognize that vaccines can be anxiety-provoking and painful, very few primary care professionals have plans in place to decrease pain

and anxiety for patients while receiving vaccinations in the office (Brady, Avner, & Khine, 2011). Thus, there is a need for provider education that implementing pain and anxiety control interventions could improve patient experience vaccines. By disseminating the work of this project through publication, poster exhibition, and conference presentations, primary care providers will be educated not only on the importance of having pain and anxiety reducing methods in their offices, but also about the attractiveness of VR for patients.

Organization and Stakeholders

For the specific organization where the project implementation took place, the introduction of the VR inspired a focus on patient pain and anxiety management during vaccination. They had reported previously using techniques such as bubbles or pinwheels to help distract the children, but the VR had a much more positive effect on the patient experience. The office manager plans to buy one or two VR units to have in the office based on the findings from this project.

Sustainability of the Project

Sustainability for an intervention is an important consideration in whether to implement the change further. Sustainability needs to be measured by the effectiveness of the change, ease of implementation, and cost of the program. Considering the significant decrease in both pain and anxiety for pediatric patients receiving vaccinations when using the VR, the project has shown its effectiveness. The VR is relatively easy to implement in a primary care office, with the practice only needing to buy a set of goggles, hygienic cover, and obtain a smartphone. The costs of these elements are affordable, with the goggles and cover costing about \$100 and older version smartphones can be donated or purchased cheaply online. Another alternative is an all-

in-one set that does not rely on the use of a smartphone, which can cost as low as \$199 (Best Buy, 2018). Thus, implementing VR in a primary care office meets the standards of effective, easy, and affordable, and so should be a sustainable change in the office.

Sustainability of Future Research

While this pilot project found significant decreases in pain and anxiety for children using the VR during vaccination, there is still many areas to broaden this research. This project was centered in just one practice in a relatively affluent area of New Jersey. Future analysis should include more subjects to see if the findings are generalizable to a larger population. In addition, the technology should be implemented in a wider range of ages, such as with children ages 8 and up, and in additional geographic areas, such as in other counties in the state or other areas of the country to see if the findings from this specific pediatric office are replicated.

Conclusion

This pilot project has shown that the use of virtual reality during vaccinations significantly decreases both pain and anxiety for pediatric patients aged 10-21. This intervention is relatively inexpensive and attractive for patients to use, making it an ideal intervention for this age group. The VR makes the procedure less stressful for patients, and so will ideally increase their compliance with future vaccinations. Increased vaccination compliance will benefit not only the personal health of the patient but lead to improved public health through decreases in disease transmissions. Dissemination of these findings, through formal education or inclusion in professional toolkits, will allow for more wide spread adoption into pediatric practice.

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Tables & Figures

Table 1: Staff Concerns and Mitigation

	Staff Concern	Mitigation Plan
1	Using the VR will impede on work flow, making vaccinations take longer	DNP student worked with MA to optimize workflow; VR checked for functionality prior to entering subject room to prevent delays due to VR system not working
2	Tool needs to be cleaned between patient use	DNP student purchased vinyl face cover to facilitate easier cleaning; appropriate alcohol wipes were purchased and used in between subjects
3	Wearing the headset for longer than a couple minutes can give a headache	According to protocol, subjects only used VR for up to 2 minutes, so extended use should not be a problem; DNP student coordinated with MA to ensure subject is only using VR for that period and not any longer
4	Waiting for the sea animals to come in the Ocean Rift game can be anxiety producing (user is only looking at open ocean for some of the functions)	DNP student reviewed all game options and found ones where the scene is most interactive; before subject use, DNP student ensured that animals are in the scene before setting up the equipment on the subject

Table 2: Descriptive Data

		Control (n=52)	VR (n=52)
Age		13.9	13.2
Sex	Male	30	28
	Female	22	24
Race	White	31	32
	Black	9	12
	Hispanic	5	1
	Asian	7	7
Type of immunization	Flu	46	40
	HPV	11	17
	Meningitis	8	11
	Meningitis B	4	8
	TDaP	6	4
	Other	1	2
Baseline Anxiety		4.13	4.65
Average # of Immunization		1.46	1.62

Table 3: Analysis Results

Group	Average Pain	Average Procedure Anxiety	Average Decrease from Baseline Anxiety
Control	3.06	3.98	0.15
VR	2.31	2.04	2.62
Mann-Whitney U score (P value)	1057 ($p=0.052$)	750.5 ($p=0.000077$)	561 ($p=0.0000002083$)

Table 4: Variable Correlations, significant correlations highlighted

		Age	Race	Sex	Number Vaccine	Base Anxiety	Vaccine Anxiety	Pain	Change in Anxiety	Flu	HPV	Meningitis	Meningitis B	TDaP	Other
Procedure Anxiety	Correlation Coefficient	0.038	-0.071	0.019	0.096	.499**	1.000	.654**	.436**	0.002	0.162	-0.040	0.117	-0.024	-0.030
	Sig. (2-tailed)	0.703	0.472	0.849	0.331	0.000		0.000	0.000	0.983	0.101	0.688	0.237	0.808	0.763
Pain	Correlation Coefficient	-0.014	-0.060	-0.113	.342**	.422**	.654**	1.000	0.154	0.009	.279**	0.142	.236*	-0.003	-0.025
	Sig. (2-tailed)	0.890	0.548	0.255	0.000	0.000	0.000		0.118	0.924	0.004	0.151	0.016	0.978	0.799
Change in Anxiety	Correlation Coefficient	0.085	0.069	-0.004	-0.034	-.497**	.436**	0.154	1.000	0.030	0.017	-0.065	-0.084	-0.011	-0.014
	Sig. (2-tailed)	0.393	0.485	0.969	0.732	0.000	0.000	0.118		0.760	0.860	0.513	0.399	0.912	0.892

Table 5: Regression Results

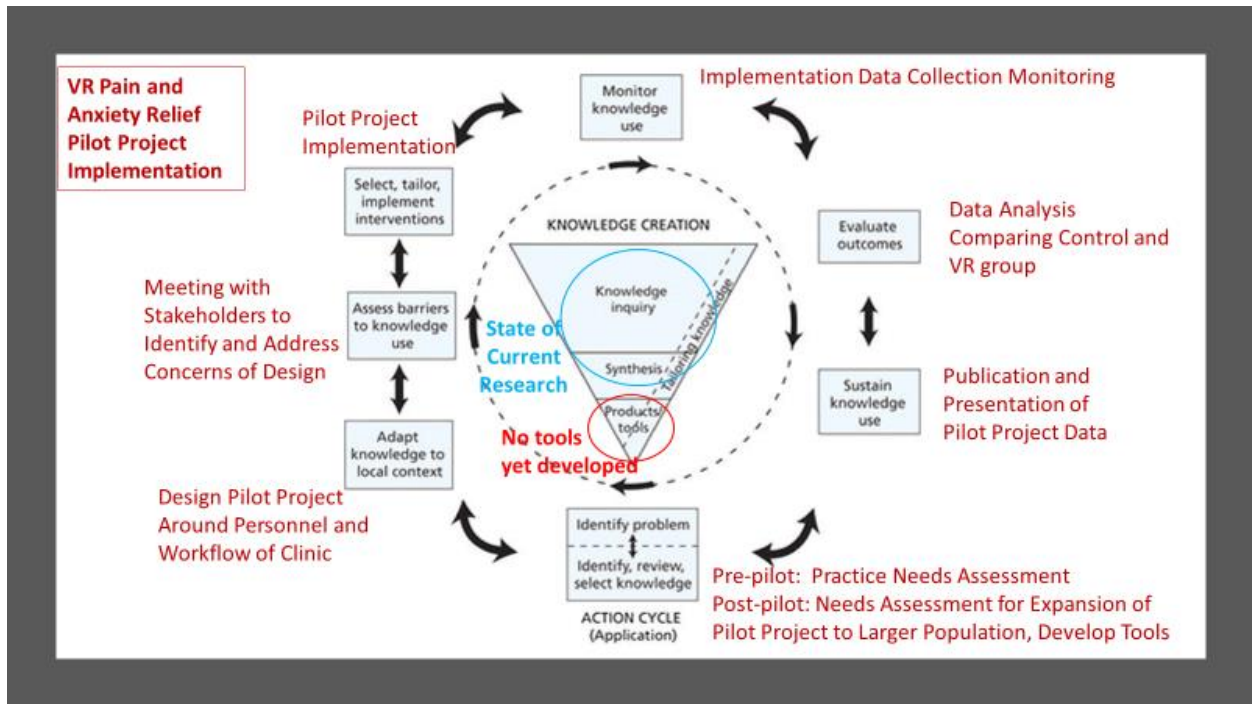
		Coefficients				
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.470	0.313		4.699	0.000
	Baseline Anxiety	0.276	0.061	0.409	4.522	0.000
2	(Constant)	1.214	0.302		4.015	0.000
	Baseline Anxiety	0.232	0.059	0.343	3.954	0.000
	Painful Vaccine	1.198	0.320	0.325	3.745	0.000
3	(Constant)	2.759	0.491		5.624	0.000
	Baseline Anxiety	0.246	0.055	0.364	4.459	0.000
	Painful Vaccine	1.389	0.304	0.377	4.570	0.000
	Group	-1.118	0.290	-0.314	-3.859	0.000

Table 6: Qualitative Analysis

Theme	Sample Statement	N	Percentage
Enjoyment of the experience	"It was fun and cool to use"	43	82.69%
Helpfulness of VR	"Last year it took 45 minutes for them to give him the flu shot, this is so much better"	31	59.62%
Surprise	"Did I get all of them already?"	17	32.69%
Future use	" I want to do it for all my shots"	5	9.62%
Remaining anxiety	"I was anxious not seeing the shot"	4	7.69%

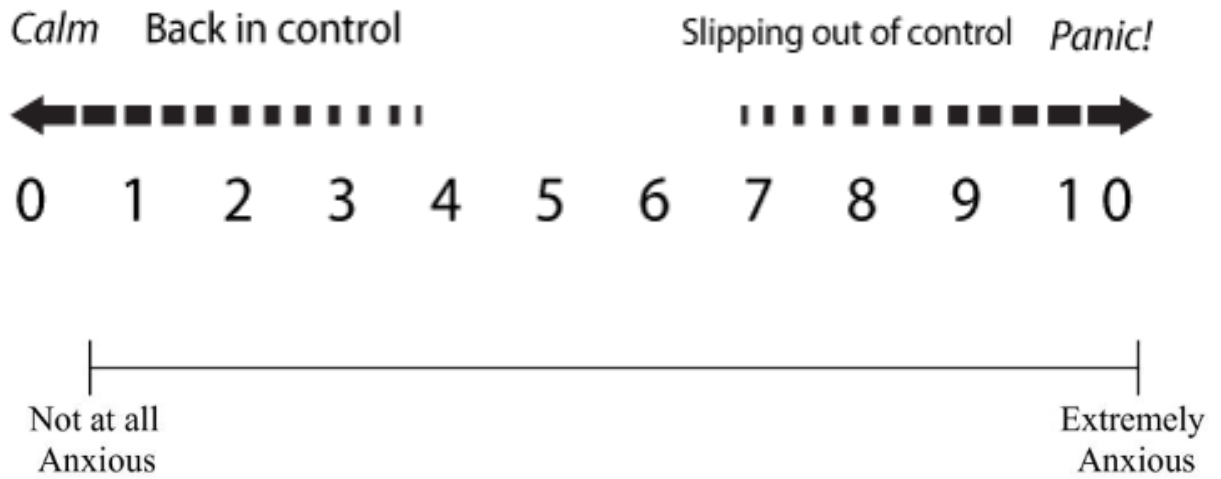
Appendices

Appendix A: Project Framework

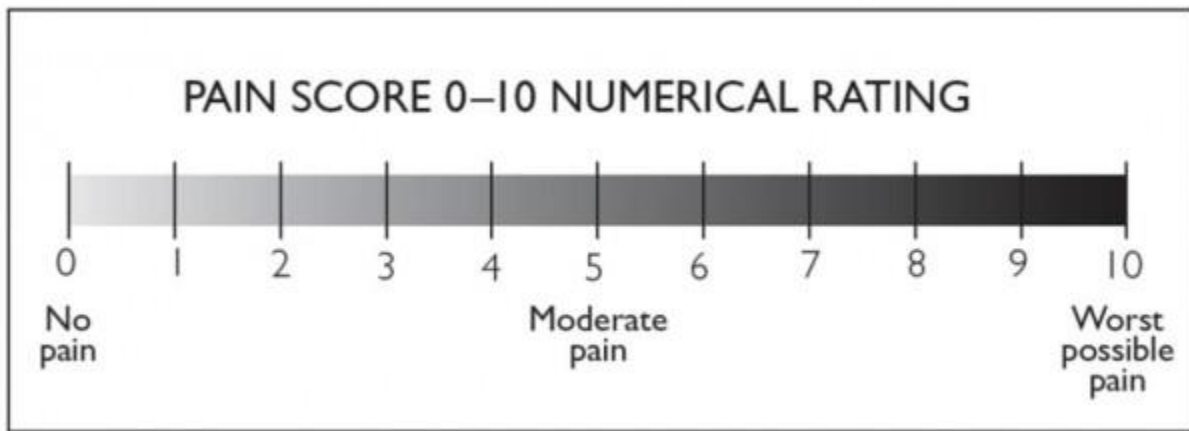


Appendix B: Evaluation Tools

Numeric Scale for Anxiety



Numeric scale for Pain





PLANNED VR DAYS

- (To be determined once schedule is finalized)

THIS FALL, YOU CAN TRY VIRTUAL REALITY WHEN GETTING YOUR SHOTS

Research has shown that distraction is an effective technique in decreasing pain and anxiety during medical procedures. Virtual Reality is one of the most effective and techniques available today. We want to test this technology in helping ease pain and anxiety that can come with vaccinations. On select days, Ms. Julia Higashio, a doctoral student at Rutgers School of Nursing, will be present to conduct research on how effective VR is during vaccinations.

On select days, Ms. Julia Higashio, a doctoral student at Rutgers School of Nursing, will be present to conduct research on how effective VR is during vaccinations. If you are between the ages of 13-21, and are interested in participating in this trial, please let the office know and you can be scheduled for a vaccine appointment on one of the days listed.

Appendix D: Subject Informational Sheet, to be given at patient registration



This office is currently participating in a research project in conjunction with a pediatric nursing doctoral student at Rutgers University School of Nursing. For this study, we are looking to see if using virtual reality (VR) can help decrease pain or anxiety during vaccinations. You are receiving this paper because you are due to receive a vaccine during your visit today. If you are interested in participating in this study, please indicate so to the receptionist so you can be given further information. If you do not indicate interest, we will assume you do not wish to participate in the project.

Thank you very much for your consideration.



Appendix E: Consent Forms



PARENT/GUARDIAN CONSENT

TITLE OF STUDY: Use of Virtual Reality to Decrease Pain and Anxiety During Vaccination

Principal Investigator: Julia Higashio, RN, BSN

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer your child for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to allow your child to take part in the study, you will be asked to sign this informed parental consent form.

The study investigator, Julia Higashio, will also be asked to sign this informed parental consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your child's legal rights by volunteering for this research study or by signing this consent form.

Why is this study being done?

We want to see if the use of virtual reality (VR) will decrease pain and anxiety during vaccinations

Why has your child been asked to take part in this study?

He or she is receiving a vaccine today

Who may take part in this study? And who may not?

Children and young adults ages 10-21, and their parent/guardian can participate in the study. But, you cannot participate if the child has ever had a seizure, or experienced motion sickness or claustrophobia (fear of small spaces)

How long will the study take and how many subjects will participate?

Your part will only about 5 minutes, and we are recruiting 100-150 participants

What will you and your child be asked to do if he/she takes part in this research study?

Your child will be asked to rate your anxiety before the vaccine. He or she will then use the VR for 60-90 seconds before and up to 30 seconds after the vaccination. We will ask his/her pain level from the vaccine after the VR is removed. Your child will also be asked about your experience. Your participation will involve giving your feedback on the experience.

What are the risks and/or discomforts your child might experience if he/she takes part in this study?

Protections will be put in place to reduce risk however there are certain risks associated with the study

including feeling dizzy or nauseous. There is also a rare chance of inducing claustrophobia or seizure.

What are your alternatives if you don't want your child to take part in this study?

There are no alternative treatments available. Your alternative is not to allow your child to take part in this study.

Will there be any cost to you for allowing your child to take part in this study?

There is no cost to participate in this study.

Will you or your child be paid for allowing your child to take part in this study?

Your child will not be paid for their participation in this research study.

How will information about your child be kept private or confidential?

All efforts will be made to keep your child's personal information in their research record confidential, but total confidentiality cannot be guaranteed. Papers will be stored in a locked file cabinet at Rutgers University. Individual answers to questions will be saved on a password protected USB drive.

What will happen if you do not wish for your child to take part in the study or if you later decide not to keep your child in the study?

Participation in this study is voluntary. You may choose not to allow your child to participate or you may change your mind about their participation at any time.

If you do not want your child to enter the study or decide to stop your child's participation, your child's relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which your child is otherwise entitled.

You may also withdraw your consent for the use of data already collected about your child, but you must do this in writing to Ms. Higashio at jpurn@sn.rutgers.edu

Who can you call if you have any questions?

If you have any questions about your child taking part in this study or if you feel your child may have suffered a research related injury, you can contact the study PI, Ms. Higashio at jpurn@sn.rutgers.edu. If you have any questions about your child's rights as a research subject, you can call the Rutgers *IRB Director* at (973)-972-3608

What are your rights if you decide to allow your child to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOUR CHILD FOR A RESEARCH STUDY

Information about your child is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your child's health information in this research study. Your child's information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your child's health information. If you sign this parental consent form, you agree to let the researchers use your child's information in the research and share it with others as described below.

What is the purpose of this research study and how will my child’s health information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your child’s health information for this study is to help researchers answer the questions that are being asked in the research.

What information about my child will be used?

- What type of vaccine you will receive today
- His/her health history will be checked to make sure he/she does not have conditions that would not allow him/her to participate

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my child’s research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your child’s information. But, if you do not give permission, your child cannot take part in this research study.

If I say yes now, can I change my mind and take away my child’s permission later?

Yes. You may change your mind and not allow the continued use of your child’s information (and to stop taking part in the study) at any time. If you take away permission, your child’s information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your child’s information in the research, you must write to the researcher and tell him or her of your decision at jpurn@sn.rutgers.edu

How long will my child’s permission last?

Your permission for the use and sharing of your child’s health information will last until the end of the study

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I am the [] parent or [] legal guardian of _____ (name of child) and I agree for my child to take part in this research study.

Subject/Child's Name: _____

Parent's Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: _____

Signature: _____ Date: _____



ADOLESCENT ASSENT

*TITLE OF STUDY: Use of Virtual Reality to Decrease Pain and Anxiety During Vaccination
Principle Investigator: Julia Higashio, RN, BSN*

Who are we and why are we meeting with you?

I am Julia Higashio and I am a student at the Rutgers, The State University of New Jersey, School of Nursing in the Department of Pediatrics. I am the study investigator on a research study. We would like to tell you about a study that involves children like yourself. We would like to see if you would like to participate in this study.

What is this research study about?

We want to see if the use of virtual reality (VR) will decrease pain and anxiety during vaccinations

Why have I been asked to take part in this study?

You are receiving a vaccine today.

Who can be in this study? And who may not? How long will the study take?

Children and young adults ages 10-21, along with their parents, can participate in the study. But, you cannot participate if you have ever had a seizure, or experienced motion sickness or claustrophobia (fear of small spaces)

What will happen to me if I choose to be in this study?

You will be asked to rate your anxiety before the vaccine. You will then use the VR for 60-90 seconds before and up to 30 seconds after the vaccination, and we will ask your pain level from the vaccine after the VR is removed. You and your parent will also be asked about your experience

Will I get better if I am in the study?

The VR may decrease your pain and fear from the vaccine. However, it is possible nothing will happen.

Can something bad happen to me or will I feel uncomfortable if I take part in this study?

Protections will be put in place to reduce risk however there are certain risks associated with the study including feeling dizzy or nauseous. There is also a rare chance of inducing claustrophobia or seizure.

What if I don't want to take part in this study?

You don't have to be in this study if you don't want to. No one will get angry or upset if you don't want to be in the study. Just tell us. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Will I be given anything to take part in this study?

No, you will not receive anything.

What if I have questions?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. Here are the ways to reach us:

If I have questions about the study I can contact Ms. Higashio at jpurn@sn.rutgers.edu

If I have any questions about my rights as a research subject, I can call the Rutgers Institutional Review Board at (973)-972-3608.

What are my rights if I decide to take part in this research study?

I understand that I have the right to ask questions about any part of the study at any time. I understand that I should not sign this form unless I have had a chance to ask questions and have been given answers to all of my questions.

I have read this entire form, or it has been read to me, and I believe that I understand what has been talked about. All of my questions about this form and this study have been answered.

I agree to take part in this research study.

Subject Name: _____

Subject Signature: _____ *Date:* _____

Signature of Investigator or Responsible Individual:

To the best of my ability, I have explained and discussed the full contents of the study, including all of the information contained in this consent form. All questions of the research subjects and those of his/her parent(s) or legal guardian have been accurately answered.

Investigator/Person Obtaining Assent: _____

Signature: _____ *Date:* _____

Adult Consent for Subjects 18 Years or Older



CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Use of Virtual Reality to Decrease Pain and Anxiety During Vaccination

Principal Investigator: Julia Higashio, RN, BSN

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part in it, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this informed consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?

Ms. Higashio is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research.

Ms. Higashio may be reached at jpurn@sn.rutgers.edu. Ms. Higashio will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

We want to see if the use of virtual reality (VR) will decrease pain and anxiety during vaccinations

Who may take part in this study and who may not?

Children and young adults ages 10-21 can participate in the study. But, you cannot participate if you have ever had a seizure, or experienced motion sickness or claustrophobia (fear of small spaces).

Why have I been asked to take part in this study?

You are receiving a vaccination today

How long will the study take and how many subjects will take part?

The study will last for 2-3 months, and we are recruiting 100-150 participants. Your part will only about 5 minutes.

What will I be asked to do if I take part in this study?

You will be asked to rate your anxiety before the vaccine. You will then use the VR for 60-90 seconds before and up to 30 seconds after the vaccination, and we will ask your pain level from the vaccine after the VR is removed. You will also be asked about your experience.

What are the risks and/or discomforts I might experience if I take part in this study?

Protections will be put in place to reduce risk however there are certain risks associated with the study including feeling dizzy or nauseous. There is also a rare chance of inducing claustrophobia or seizure.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be reduction of your pain and anxiety from the vaccine. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

The alternative is standard office procedure during the vaccination

Will there be any cost to me to take part in this study?

No, there is no cost to participate

Will I be paid to take part in this study?

No, you will not be paid to take part in the study

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The consent forms will be stored in a locked filing cabinet, and your answers will not be linked with your name. All individual answers to questions will be stored in a password protected USB drive.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Ms. Higashio at jpurn@sn.rutgers.edu

Who can I call if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the study PI, Julia Higashio at jpurn@sn.rutgers.edu

If you have questions about your rights as a research subject, you can call the IRB Director at: Newark HealthSci (973)-972-3608; or the Rutgers Human Subjects Protection Program at (973)972-1149 in Newark or (732)235-8578 in New Brunswick.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- What type of vaccine you will receive today
- Your health history will be checked to make sure you do not have conditions that would not allow you to participate

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has

already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to Ms. Higashio tell her of your decision at jpurn@sn.rutgers.edu

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the study.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name: _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____

Appendix F: Project Timeline

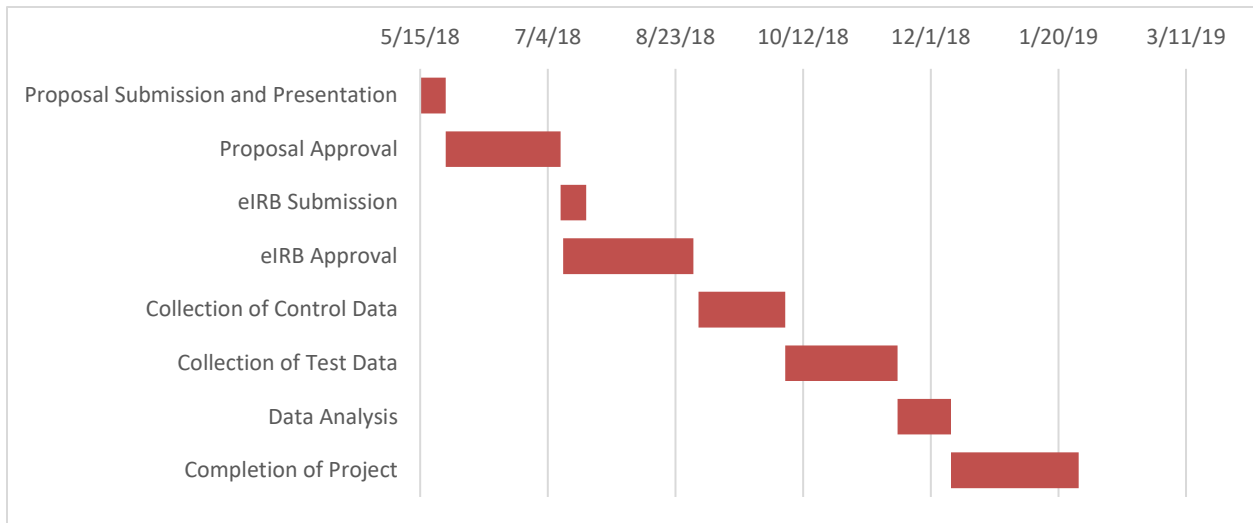


Table of Evidence

Article Number	Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study Findings	Limitations	Evidence Level & Quality
1	Silverberg Z, Silverberg M, La Puma J (2017)	Control trial without randomization	244 children receiving influenza vaccination in outpatient clinic age 5-16	Using VR for approximately 30 seconds before, during, and 30 seconds after vaccination was associated with a 45% to 74% decrease in pain (using Wong-Baker scale), as measured by patients, parents, and nurse giving inoculation	They did not measure anxiety or level of vaccine fear in children, did not break down results by age (difficult to compare 5 and 16-year-old)	Level III, B good quality because of large sample size and assessment of patients, parent and nurses

2	Gold, J. I. Mahrer, N. E. (2017)	RCT	143 triads (patient, parent, and phlebotomist) used VR as a distraction during blood draws in LA area hospital. Age of patient ranged from 10-21; they played the game Bear Blast on Samsung gear VR	VR significantly reduced pain and anxiety in the patients from self-report data of patient and parent. Secondary analysis examined the effects of VR while looking at base anxiety levels. They children with high anxiety had significant, large decreases in procedural pain. For children with low pre-procedural anxiety, the effects of VR were not 0significant. Thus, they conclude that VR works best for children with higher baseline procedural anxiety	Age range starts at 10, so effects of VR on younger children not studied; the sample size was not large enough to generalize findings outside this group of children using this particular device and this particular game	Level II: RCT, B good quality because of detailed study design and assessment, but sample size is still too small for wide generalizations
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3	<p>Won, A. S. Bailey, J. Bailenson, J. Tataru, C. Yoon, I. A. Golianu, B. (2017)</p>	Literature review	<p>The studies summarized in this article are from disparate sources, from the hospital to outpatient. Commonality is pediatric patients age 5-21 and use of VR as distraction</p>	<p>(Won et al., 2017) This is a systematic review article on the current state of VR use in pediatric pain management. They review current findings, VR use in procedural, acute, and chronic pain. They also summarize the current status of the technology and implications for future use</p>	No primary research, combination of research summary and report of current VR capabilities	Level V: Literature review, A high quality due to breadth of coverage (research findings and technology availability)
4	<p>Hua, Y. Qiu, R. Yao, W. Y. Zhang, Q. Chen, X. L. (2015)</p>	RCT pilot program	<p>Location: pediatric center in a tertiary hospital; Sample size: 65; Sample details: children aged from 4 to 16 years, with chronic wounds on their lower limbs that need dressing changes</p>	<p>Pain during dressing change decreased by an average of 42% in the VR group compared to standard distraction (measured before, during, and after dressing change).</p>	Small sample size so generalization statements cannot be made	Level II RCT, C low quality because of sample size

5	<p>McMurtry, C. M. Pillai Riddell, R. Taddio, A. Racine, N. Asmundson, G. J. Noel, M. Chambers, C. T. Shah, V. HelpinKids, Adults, Team (2015)</p>	Expert Opinion	<p>This is a compilation article from leading pain management experts exploring the issue of vaccination pain and needle phobia in pediatrics. They cite current research to support pain relief interventions during vaccination</p>	<p>They found that vaccinations provoke significant pain and anxiety in the patient, but that pain is usually not addressed in primary care. They determined that needle phobia is an important issue in pediatrics because it leads to increased declinations of vaccines. They identified a gap between knowledge and intervention</p>	<p>This is a non-research article, so there are no new studies or data</p>	<p>Level VII: Expert opinion, A high quality due to detailed citations and references supporting evidence</p>
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6	<p>Birnie, K. A.Noel, M. Parker, J. A. Chambers, C. T. Uman, L. S. Kisely, S. R. McGrath, P. J. (2014)</p>	<p>Systematic review and Meta-analysis</p>	<p>Synthesis of 26 distraction and 7 hypnosis trials. Inclusion criteria: 1) randomized controlled trials; 2) included children aged 2–19 years of age undergoing a needle-related procedure; 3) published in a peer-reviewed journal; 4) included a psychological intervention against a control; and 5) assessed pain and/or anxiety using a reliable and valid measure during or following the needle procedure</p>	<p>The study confirmed that distraction is an effective tool in mitigating pain from needle procedures. They also noted that child engagement with the distraction is key to the efficacy of the distraction, with a significant association found between child engagement and decrease in pain/distress</p>	<p>This study looked at all forms for distraction, so it is not VR specific; Because different subtypes of distraction were included in the meta-analysis (with low or very low quality of evidence) and with varying levels of engagement, results may be biased downward due to inclusion of interventions that are not as effective as others; General limitation of comparing pain in children of different ages and development</p>	<p>Level I: Systematic Review of RCT, A high quality due to meta-analysis inclusion and thoroughness of primary data</p>
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7	Kipping, B. Rodger, S. Miller, K. Kimble, R. M. (2012)	RCT pilot program	41 adolescents (age 11-21) in burn unit within tertiary hospital	Patients were randomly divided into VR and non-VR groups for burn wound dressing change. In VR group, all pain measurements (self-report, nurse FLACC and vital signs) were lower than control, but not significantly so. Use of rescue drug Entonox was significantly lower in VR group than in control	Small sample size so relative small effects of VR on pain cannot be detected, results cannot be generalized	Level II RCT, C low quality because of sample size
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8	Brady, K. Avner, J. R. Khine, H. (2011)	Physician survey	Survey of 70 primary care pediatric physicians in outpatient clinics	Physicians were asked to quantify their perceptions of pain and anxiety for 4-6-year-old patients receiving vaccinations. They estimated that these patients experienced significant pain (5.7 on scale of 1-10) and anxiety (7.7 on scale of 1-10). However, only 8 physicians (11%) included pain relief measures in their practice, demonstrating gap in treatment for these patients	Physician ascribed values were not compared to actual values from children to validate that their perceptions were reality	Level VI: Evidence from a single descriptive study, B good quality because scientific assessment of current views of pediatric physicians
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9	Han, H. R. (2009)	Systematic review	<p>Systematic review of pediatric anxiety measurement and implications using PubMed. Original search resulted in 224 articles. Articles without full text links or lacking original research were excluded, leading to 69 articles. Of those, studies were further excluded for age range issues, disease-specific analysis (i.e. cystic fibrosis patients), general anxiety versus state anxiety, leaving 14 studies for measuring anxiety.</p>	<p>They found that the STAI validated and take less time to complete than other surveys, and would be a beneficial tool for assessing state anxiety</p>	<p>Sample sizes in the original journal articles were small, so might be an issue in generalizing the findings even though they were consistent over the small studies</p>	<p>Level I: Systematic Review, B good quality because exclusion criteria appears overly stringent</p>
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10	Nilsson, S. Finnstrom, B. Kokinsky, E. Enskar, K. (2009)	Pilot RCT	The sample size: 42 children and adolescents, 5-18 years of age. The study took place on an inpatient oncology unit	Both quantitative and qualitative data were gathered to determine pain level for children during venous access in oncology patients. They did not find any statistically significant differences between the case and control groups in quantitative pain values, but qualitative analysis of questionnaires after the project showed generalized support of the VR and that patients reported better general experiences with it versus standard distraction	Qualitative data collected via interviews were not uniform throughout the study; study estimates were not precise so the validity of the insignificance in the quantitative cannot be determined	Level II RCT, C low quality because of sample size
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11	Gold, J. I. Kim, S. H. Kant, A. J. Joseph, M. H. Rizzo, A. S. (2006)	RCT pilot program	20 children undergoing IV placement prior to MRI	Control group had 4-fold increase in pain during IV placement compared to VR group (not statistically significant). VR group also showed evidence of lower anxiety and more satisfaction with the procedure	Small sample size, relatively low pain score meant that detecting statistical significance was not possible	Level II RCT, C low quality because of sample size
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